#13

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P&G Case Docket No. 8141

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of

Inventor(s): MATTHEW JOSEPH DOYLE, ET AL.

Serial No. : 09/607,602 Group Art Unit: 1644

Date Filed: June 30, 2000 Examiner: A. DeCloux

Title: PROMOTING WHOLE BODY HEALTH Confirmation No. 8543

APPEAL BRIEF

Attn: BOARD OF APPEALS
THE ASSISTANT COMMISSIONER FOR PATENTS
Washington D.C. 20231

Dear Sir:

The present Appeal Brief is submitted in support of the Notice of Appeal filed February 13, 2003.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the present application, The Procter & Gamble Company.

II. RELATED APPEALS AND INTERFERENCES

There are no interferences known to the Appellants, the Appellants' undersigned representative or the assignee which will directly affect or be directly affected by or having a bearing on the Board's decision on the present appeal.

A Notice of Appeal was filed on filed January 17, 2003 in connection with a related application, Serial No. 09/607,240 filed on June 30, 2000, and an Appeal Brief was filed on March 17, 2003.

III. STATUS OF THE CLAIMS

Method Claims 2-4 and 7 are pending in the present application and stand rejected. Claims 1, 5 and 6 have been canceled. A complete copy of the pending claims is set forth in the Appendix.

IV. STATUS OF AMENDMENTS

Applicants' amendment of Claims 2-4 and 7 filed on June 24, 2002 and resubmitted by facsimile transmission on July 29, 2002, was entered by the Examiner. Claim 1 was cancelled. Claims 5 and 6 were also cancelled in response to the finality of the restriction requirement in the Office Action dated December 27, 2001. No amendments have been filed subsequent to the final rejection of Claims 2-4 and 7 set forth in the Office Action dated October 21, 2002.

V. SUMMARY OF THE INVENTION

The present invention as now claimed is directed to a method of promoting whole body health in human and other animal subjects. By "whole body health" as used herein is meant overall systemic health characterized by a reduction in risk of development of major systemic diseases and conditions including cardiovascular disease, stroke, diabetes, severe respiratory infections, premature births and low birth weights (including post-partum dysfunction in neurologic/developmental function), and associated increased risk of mortality.

The method involves topical administration to the oral cavity of the subject, as opposed to systemic administration, of a composition comprising one or a mixture of selected H2 antagonist(s), optionally with an additional therapeutic agent selected from antimicrobial/antiplaque agents, biofilm inhibiting agents, antibiotics; analgesics and local anesthetic agents; dentinal desensitizing agents; odor masking agents; and mixtures thereof. By "topical administration" is meant that in the ordinary course of usage, the composition is not intentionally swallowed for purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues. The present claims are based on Applicants' discovery of a new use for a method involving topical treatment of the oral cavity. Specifically, Applicants have discovered that topical administration to the oral cavity of compositions comprising particular H2 antagonist(s) promotes systemic health. In particular, the present method effectively decreases etiologic factors that contribute to development of certain systemic diseases such as heart disease. By decreasing the etiologic factors for a systemic disease, the risk of developing such a disease is also decreased leading to better overall systemic health for the subject. The systemic benefits of the present method involving topical administration of H2 antagonist(s) are totally unexpected, since systemic effects would be expected to be derived from systemic administration of such agents rather than from topical administration.

The Board's attention is directed to the attached declaration by present inventor Robert E. Singer, Jr., presenting findings relevant to the mechanism of action of topical H2 antagonists. The present claims are based on the discovery that topical treatment of oral tissues with H2 antagonists serves to increase the gingival barrier function of the periodontal tissues. From a series of studies conducted under Mr. Singer's direction, it has been demonstrated that topical H2 antagonists (1) increase gingival crevicular polymorphonuclear (PMN) function for the phagocytosis and killing of bacterial pathogens; (2) elevate the levels of gingival crevicular antibodies during experimental periodontitis; and (3) increase the levels of gingival crevicular fluid (GCF) IgA, a marker for the protective gingival tissue response. Taken together, these findings indicate that H2 antagonists enhance the function of key mechanisms of the gingival barrier function.

From these new findings, it is evident that the topical application of H2 antagonists to oral tissues represents a unique and unanticipated approach to increasing the barrier function of gingival tissues. The abililty of H2 antagonists to increase the natural barrier function of gingival tissues is an extremely important benefit in as much as this unique mechanism of action enables providing not only a benefit vs. periodontal disease but unexpectedly also represents an effective approach to preventing oral pathogens and their products from entering into either the gingival tissues or the systemic circulation. Consequently, topical application of H2 antagonists affords unanticipated benefits for preventing oral pathogens from prompting the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.

As defined in Claim 2 and disclosed at pages 12-25, the present method comprises topically administering a topical oral composition comprising a safe and effective amount of a host-response modulating agent and a pharmaceutically acceptable oral carrier, wherein the host-response modulating agent is a H2-antagonist.

Claims 3 and 4 further define the method of Claim 2. According to Claim 3 and as disclosed at pages 38-41, the composition for use in the present method is in a form selected from the group consisting of in a form selected from the group consisting of a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, dental implement, and a pet care product. According to Claim 4, the H-2 antagonist is selected from the group consisting of cimetidine, etintidine, ranitidine, ICIA-5165, tiotidine, ORF-17578, lupitidine, donetidine, famotidine, roxatidine, pifatidine, lamtidine, BL-6548, BMY-25271, zaltidine, nizatidine, mifentidine, BMY-25368 (SKF-94482), BL-6341A, ICI-162846, ramixotidine, Wy-45727, SR-58042, BMY-25405, loxtidine, DA-4634, bisfentidine, sufotidine, ebrotidine, HE-30-256, D-16637, FRG-8813, FRG-8701, impromidine, L-643728, HB-408, and mixtures thereof.

As defined in Claim 7 and disclosed at pages 26-27, the compositions optionally comprise an additional therapeutic active selected from the group consisting of antimicrobial/antiplaque agents, biofilm inhibiting agents, antibiotics; analgesics and local anesthetic agents; dentinal desensitizing agents; odor masking agents; and mixtures thereof.

VI. ISSUE ON APPEAL

The single issue presented for review by the Board in the present appeal is the rejection of Claim 2 under 35 USC § 102(b) as being anticipated by Tsujita et al. (JP 04089428A) and of Claims 2-4 and 7 under 35 USC § 102(b) as being anticipated by Pan et al. (WO 97/16159) and by commonly owned Singer et al. (US 5,364,616). It is contended in the Office Action that the present claimed use of promoting systemic or whole body health is inherent in the referenced methods.

Pan et al. (WO 97/16159) discloses oral compositions containing an H2 receptor antagonist and antimicrobial oils that are effective in preventing and treating gingivitis and peniodontitis and a method of preventing or treating inflammations in the oral cavity by applying an effective amount of the oral composition to the oral cavity. Inflammations in the oral cavitv include such conditions as gingivitis and periodontitis.

Singer et al. (US 5,364,616) teaches a method of treatment and prevention of gingivitis and periodontitis by administering an oral composition comprising a H2 antagonist. Optionally, the Singer et al. composition may comprise an antimicrobial agent and used for treating dental plaque.

Tsujita et al. (JP 04089428A) discloses a polymorphonuclear leukocyte activator comprising histamine H2 acceptor antagonist such as brimamid, metiamide, cimetidine or ranitidine as active ingredients, which improves gingivitis, an example of inflammation occurring by usual microorganisms. The activator is especially effective for opportunistic infection against which antibiotics and germicides are not effective.

There are no rejections under 35 USC § 103.

VII. GROUPING OF CLAIMS

With respect to the above-noted issue on appeal, Applicants group Claims 2-4 together. Claim 7 stands separately.

VIII. ARGUMENTS

As will be set forth in detail below, the methods of promoting whole body health defined by Claims 2-4 and 7 are patentably distinct from Pan et al. (WO 97/16159),

Singer et al. (US 5,364,616) and Tsujita et al. (JP 04089428A). Accordingly, the rejection of the claims under 35 USC § 102(b) should be reversed. Favorable action by the Board is respectfully requested.

Claims 2-4 and 7 are rejected under 35 USC § 102(b) as being anticipated by Pan et al. (WO 97/16159) and by commonly owned Singer et al. (US 5,364,616). Claim 2 stand rejected under 35 USC § 102(b) as being anticipated by Tsujita et al. (JP 04089428A). The Examiner contends that the instant claims recite the same method steps and thus, the results of the method steps are inherent. It is further noted in the Office Action that newly discovered results of known processes directed to the same purpose are not patentable because the court recognized in *In re Woodruff* 16 USPQ2d 1934 1936, that it is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. The Examiner further cites *Verdegaal Bros., Inc. v. Union Oil Co. of California* 814 F.2d 628, 632-33, 2 USPQ2d 1052, 1054 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987) and *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375, 197 USPQ2d 134, 139 (5th Cir. 1978).

The Examiner clearly recognizes that the present method provides a new benefit or new use but contends that "the instant case does not present a situation in which the new use of a process should be considered limiting," citing *Bristol-Myers Squibb v. Ben Venue Laboratories* 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001).

Firstly, Applicants submit that the rejection of the present claims under 35 USC § 102(b) as being anticipated by Pan et al. (WO 97/16159); Singer et al. (US 5,364,616); and Tsujita et al. (JP 04089428A) is improper, because none of the citations discloses all the material elements of the claims. Specifically there is no disclosure whatsoever in any of the citations of the "new use" of the present method, i.e., promoting whole body or systemic health. As stated in *In re Marshall* 578 F.2d 301, 198 USPQ 344 (CCPA 1978):

> *Rejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed in the prior art. In re Arkley, 59 CCPA 804, 807, 455 F.2d 586, 587, 172 USPQ 524, 526 (1972). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. Soundscriber Corp. v. United States, 360 F.2d 954, 960, 148 USPQ 298, 301 (Ct.Cl. 1966).*

There is no disclosure nor any suggestion whatsoever in any of the cited art with regard to promoting systemic or whole body health much less that such systemic benefit would be provided by topically administering the present H2-antagonist containing compositions. The only disclosure in each of the citations relates to methods involving application to the oral cavity of compositions comprising a histamine-2 receptor antagonist compound for use in prevention or treatment of gingivitis or periodontitis. While the H2-antagonist containing compositions of Pan et al. also contain antimicrobial oils and the Singer et al. compositions may optionally contain an antimicrobial/antiplaque agent, the ONLY USES disclosed are for treatment of gingivitis or periodontitis, which are inflammations in the oral cavity (Pan et al. and Singer et al.) and additionally dental plaque (Singer et al.). Tsujita et al. only discloses the use to improve gingivitis, also described therein as an example of inflammation in the oral cavity caused by microorganisms. The conditions disclosed in the citations are all localized conditions (only in the oral cavity) as opposed to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants, which are the subject of the present claims. The benefits to systemic health when the method of treatment is by topical administration as opposed to systemic administration have not been appreciated in the cited art. The present methods are based on the discovery that topical administration of selected H2-antagonists affords unanticipated benefits of preventing entry into the systemic circulation of oral pathogens and their products, which are believed to prompt the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders.

Secondly, Applicants will address the Examiner's point that the present claimed use of promoting whole body health IS NOT a "new use", but is simply a statement of purpose and intended result and is therefore not considered limiting. The Examiner has cited *Bristol-Myers Squibb v. Ben Venue Laboratories* 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001) for the proposition that:

> *[The] preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps*

of claims. The instant case does not present a situation in which the new use of process should be considered limiting because it distinguishes process over prior art.

It is respectfully submitted that the Examiner has overstated the holding in *Bristol*. The present case is distinguishable over *Bristol* in that the present "use", namely "promoting whole body health" is NOT KNOWN nor suggested by the art and is therefore, a "new use". By contrast, the "use" in *Bristol*, i.e., "treating cancer by administering paclitaxel" is the "same use" as disclosed in the applied prior art (Kris). Indeed the *Bristol* Court conceded that new uses of known process may be patentable.

> *Bristol is correct that new uses of known processes may be patentable. See 35 U.S.C. § 101 (1994) (Whoever invents or discovers any new and useful process... may obtain a patent therefore."); 35 U.S.C. § 100(b) (1994) ("The term "process" means process, art or method and includes a* ***new use*** *of a known process, machine, manufacture, composition of matter, or material.").*

The *Bristol* Court continues, "*the claimed process here is NOT directed to a new use; it is the same use, and it consists of the same steps as described by Kris* [the prior art reference].... *Bristol has done no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients. As in May, the purpose --treating cancer-- is no different from the purpose disclosed by Kris.*" [*Bristol* at 1377].

In contrast to *Bristol*, the claims of the present invention relate to a new and different use or purpose, i.e., promoting whole body health. This use IS NOT DISCLOSED in the applied prior art, and is therefore a "new use". Clearly, promoting systemic or whole body health is a different use than treating localized or nonsystemic conditions, i.e., gingivitis, periodontitis or dental plaque, as disclosed in the applied citations. Therefore, Applicants assert that the present claimed method of promoting whole body health is patentable in accordance to well-established Federal Circuit jurisprudence.

The Examiner has further cited three cases: *In re Woodruff; Verdegaal Bros., Inc. v. Union Oil Co. of California;* and *Bird Provision Co. v. Owens Country Sausage, Inc.* to

support the proposition that "it is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."

However as in *Bristol*, in each of the above referenced cases, the claimed method was directed to the same use and not a new use or purpose.

In *In re Woodruff,* the claimed use to inhibit the visible growth of fungi on refrigerated fruits and vegetables was found to be generically encompassed by the prior art (Mcgill), which is directed to a method of storing fresh and leafy vegetables in a modified atmosphere and at a lower temperature in order to maintain their fresh appearance. Woodruff's method is therefore NOT directed to a new use or purpose, but simply a more specific benefit of inhibiting the visible growth of fungi. The use of the method is still to maintain the fresh appearance of produce, which is the same use disclosed by the prior art.

In the present case, promoting systemic or whole body health can not be considered to be generically encompassed by the treatment of nonsystemic conditions of dental plaque, gingivitis and periodontitis.

In *Verdegaal Bros., Inc. v. Union Oil Co. of California,* Union Oil appealed the jury verdict that the claims of Verdegaal's fertilizer patent are valid and infringed under 35 USC §§ 102, 103. The process disclosed in Verdegaal's patent (US 4,310,343) was found by the US Court of Appeals for the Federal Circuit to be the same process and directed to the same use, i.e., making urea-sulfuric acid liquid fertilizer products, as disclosed by the teachings found in the original application for US 4,315,763 to Stoller. Stoller was prior art under §102(e) as of its filing date, which was well before the filing date of Verdegaal's application. Therefore, the jury's verdict that the '343 claims are valid and infringed was reversed by the CAFC.

Again, the present use of promoting systemic or whole body health is a new and different use from the prior disclosed use of treating nonsystemic or localized conditions of dental plaque, gingivitis and periodontitis.

In *Bird Provision Co. v. Owens Country Sausage, Inc.*, the US Court of Appeals for the Fifth Circuit affirmed the decision of the District Court for the Northern District of Texas which declared Bird's patent for making fresh pork sausage invalid on grounds of prior public use under 35 USC § 102(b) and obviousness under 35 USC § 103. There was

substantial evidence that the identical process claimed by the Bird patent had previously been used for the same purpose, i.e., producing and preserving fresh pork sausage. That the prior public users did not understand or appreciate the shelf life implications of the process does not save the Bird patent from being anticipated under § 102(b), for the discovery of the process' shelf life implications involved nothing that was new in its use or method of application. Again, the claimed use in *Bird* IS NOT A NEW USE and therefore not patentable.

By contrast, the present use of promoting systemic or whole body health is a new and different use from the prior disclosed use of treating nonsystemic or localized conditions of dental plaque, gingivitis and periodontitis.

Thirdly, Applicants respectfully traverse the Examiner's contention that the present method claims are not patentable because the results of the claimed methods, i.e., "whole body health benefits", are inherent.

The present method claims fall within the definition under 35 U.S.C. § 100(b) for a patentable "process" which means process, art or method, and includes a **new use of a known process, machine, manufacture, composition or matter or material**. (emphasis added), as acknowledged by the Court in *Bristol-Myers Squibb v. Ben Venue Laboratories*. See also *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1029 (2d Cir.), which found that Howes' claim to a method which makes possible the faithful transfer of color art work to fabric by means of treated heat transfer paper was patentable because Howes created a **new use of a known process**.

Similarly, claims drawn to a method for using either an old or "obvious" composition, wherein the method has unobvious beneficial or useful effects, have been found patentable even though the composition itself could not be patented. [See *In re Marshall* 578 F.2d 301, 198 USPQ 344 (CCPA 1978) and *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977)].

Applicants respectfully submit that the present claimed methods involving topically administering a composition comprising a H2 antagonist have new and unobvious beneficial effects, and are therefore patentable as **a new use of a process** even if such process were known. The benefits to systemic health when the method of

treatment is by topical administration of the present compositions and not by systemic administration have not been appreciated in Pan et al., Singer et al. or Tsujita et al.

Applicants further submit that the issue of inherency which the Examiner has used to make the rejection is untenable in this instance, wherein the "new use" of promoting whole body or systemic health via a method that involves topical administration of certain antibacterial actives as opposed to systemic administration is totally unappreciated in the prior art.

In *In re Shetty*, 566 F.2d 81, 83, 195 USPQ 753, 754 (CCPA 1977), Shetty's claimed method of curbing appetite by administering certain adamantane compounds was found to be patentable over prior references that disclosed administering similar compounds to achieve antiviral effects in amounts encompassing the amounts intended and claimed by Shetty for appetite suppression. The PTO had held that the compounds used by Shetty are obvious over the references and the benefit of curbing appetite claimed by Shetty is inherent. The CCPA rejected the PTO's position and reversed the rejection of Shetty's method claims for curbing appetite, stating the following:

> *We cannot accept this conclusion. The issue here is whether the claimed method of curbing appetite would have been obvious. That appellant's "amount effective to curb appetite" corresponds to or inheres in Narayanan's amount "to combat microbial infestation" does not persuade us of the obviousness of appellant's method. As this court said in In re Naylor, 54 CCPA 902, 905-06, 369 F.2d 765, 768, 152 USPQ 106, 108 (1966):*
>
> *[Inherency] is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize that inherent result.*

In *In re Marshall* (Id.), the US Court of Customs and Patent Appeals reversed the rejection of Marshall's claims on the grounds of anticipation because no single piece of prior art contained all the material elements of the claims and on grounds of obviousness because the claims described a new and unanticipated use for an existing drug. Marshall's claims were directed to a process for controlling weight using an anesthetic drug, oxethazaine, to inhibit release of the pancreatic secretory hormones, secretin and

pancreozymin, in order to control weight. The applied art was the *Physician's Desk Reference* (PDR), which taught using drugs containing the anesthetic oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome. There was no disclosure in the PDR regarding taking oxethazaine to lose weight. Therefore if a subject ever lost weight by following the PDR teachings it was an unrecognized accident. The CCPA stated:

> *An accidental or unwitting duplication of an invention cannot constitute an anticipation. In re Felton, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973).*

Similarly, the present claimed method of topically administering a composition comprising a H2-antagonist is directed to a use, i.e., promoting systemic or whole body health, which has not been disclosed in the prior art and is therefore a "new use". The applied citations do not constitute an anticipation of the present invention.

Applicants further submit that the Examiner has not established a *prima facie* case of inherency as required under MPEP 2112 and 2131.02 Section III. As stated therein:

> *"In relying upon the theory of inherency, the examiner must provide a basis in fact and or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."*

> *"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish that result or characteristic."*

There must be evidence to support the Examiner's allegation that a characteristic not disclosed in cited reference is inherent. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

As in the *Shetty* and *Marshall* cases, the Examiner has not provided any evidence whatsoever to establish that one of ordinary skill in the art would appreciate or recognize the new use of the present claimed method, i.e., promoting systemic or whole body

health. There is no disclosure or even a remote suggestion in the applied citations that a method involving topical administration of a composition containing a H2-antagonist as opposed to systemic administration would be useful in promoting systemic health. In fact, all of the cited disclosure relate to the use of H2 antagonist compounds to treat gingivitis or periodonditis and additionally inflammations in the oral cavity or dental plaque. Accordingly, the rejection of the claims under §102(b) over Pan et al., Singer et al. and Tsujita et al. cannot stand.

Finally, Applicants submit that it is well established under US patent law that a second medicinal use of a substance already suggested or known to be useful in treating a human or animal disease is patentable as a method of use. While there are numerous examples, Applicants cite the granting of US 6,100,270 (to Pfizer) with method claims for a second medicinal use, i.e., treating male erectile dysfunction, for sildenafil compositions, which have previously been patented for the treatment of many conditions including angina, hypertension and congestive heart failure (US 5,250,534 and US 5,346,901). The method in the '270 patent involves the same method of oral administration of the compositions containing the active sildenafil. The second or new use is the basis for patentability of the method.

As another example, claims to methods of treating male pattern baldness using minoxidil by topical administration were patentable as a second use (US 4,139,619 and US 4,596,812), even if minoxidil compositions had already been disclosed and patented for treating hypertension (US 3,461,461 and US 3,644,364). Claims to a process for obtaining increased meat, milk, egg or wool production in healthy animals comprising the administration of a minoxidil composition to a healthy animal were also allowed (US 4,393,065). Further, claims to a method of topically administering minoxidil for enhancing the growth of unguis (the horny cutaneous plate on the dorsal surface of the distal end of the terminal phalanx of a finger or toe, i.e., fingernail or toenail) in animals, including humans were patentable (US 4,927,626). In the '626 patent, method claims of topical administration of minoxidil for yet a new use, i.e., enhancing the growth of unguis, were patentable over prior use for growing hair. The same method with the same process steps of topical administration was found patentable by virtue of the new use.

The present method claims are likewise directed to a new or second use -- promoting systemic or whole body health-- by topical administration of H2-antagonists and are therefore, patentable in accordance with established US patent practice.

The Examiner notes that in the Applicant's cited examples of second medicinal uses of a substance, the patient population, which are subject to the methods of the first and second medicinal uses differs. The Examiner contends that in the present case, the claimed methods are applied to the same population as the referenced methods.

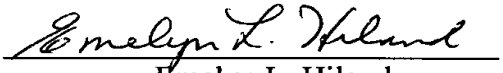
Applicants respectfully disagree with the Examiner's point. The present claimed methods are for use in all subjects regardless of their need for treatment of dental plaque, gingivitis, periodontitis or any other condition in the oral cavity. It is not a limitation of the present method that a subject is suffering from these localized conditions, since the use is to provide systemic effects, such as preventing the systemic inflammatory mechanisms and complications that contribute to systemic diseases/disorders such as atherosclerosis, stroke, diabetes, and low birth weight infants.

IX. CONCLUSION

For the reasons set forth in detail above, the method of promoting whole body health defined by Claims 2-4 and 7 is patentably distinct from Pan et al., Singer et al. and Tsujita, et al. Accordingly, the rejection of Claims 2-4 and 7 under 35 USC §102(b) should be reversed. Favorable action by the Board is respectfully requested.

Respectfully submitted,

Matthew Joseph Doyle, et al.

By 

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APPENDIX

2. A method for promoting whole body health in human and other animal subjects comprising topically administering to said subjects' oral cavity a topical oral composition comprising a safe and effective amount of a host-response modulating agent and a pharmaceutically acceptable oral carrier, wherein said host-response modulating agent is a H2-antagonist.

3. A method for promoting whole body health in human and other animal subjects according to Claim 2, wherein said composition is in a form selected from the group consisting of a mouthrinse, toothpaste, tooth gel, tooth powder, non-abrasive gel, chewing gum, mouth spray, lozenge, dental implement, and a pet care product.

4. A method for promoting whole body health in human and other animal subjects according to Claim 2, wherein said H-2 antagonist is selected from the group consisting of cimetidine, etintidine, ranitidine, ICIA-5165, tiotidine, ORF-17578, lupitidine, donetidine, famotidine, roxatidine, pifatidine, lamtidine, BL-6548, BMY-25271, zaltidine, nizatidine, mifentidine, BMY-25368 (SKF-94482), BL-6341A, ICI-162846, ramixotidine, Wy-45727, SR-58042, BMY-25405, loxtidine, DA-4634, bisfentidine, sufotidine, ebrotidine, HE-30-256, D-16637, FRG-8813, FRG-8701, impromidine, L-643728, HB-408, and mixtures thereof.

7. A method for promoting whole body health in human and other animal subjects according to Claim 2, wherein said composition topically administered to said subjects comprises an additional therapeutic active selected from the group consisting of antimicrobial/antiplaque agents, biofilm inhibiting agents, antibiotics; analgesics and local anesthetic agents; dentinal desensitizing agents; odor masking agents; and mixtures thereof.